

REMARKS

In the above-identified Office Action, the Examiner has rejected claims 1-20 as indefinite. The Examiner pointed to the word "derivative" as being indefinite. Applicant has deleted this word and, thus, believes that the claims are now definite, under 35 U.S.C. Section 112.

Applicant notes that the Examiner has not examined or commented on claims 21-25. While Applicant believes these claims to be patentable for many of the same reasons set forth below, Applicant will not comment specifically on such claims until the claims are rejected by the Examiner. Should the Examiner reject these claims, it will be a first rejection, and thus no final rejection should issue at this time.

Generally speaking, none of the documents cited by the Examiner under 35 U.S.C. 102 disclose steroidal sapogenins. Steroidal sapogenins are essentially plant-derived compounds formable by hydrolysis of steroidal saponin. A steroidal saponin is a glycosylated compound having a sugar portion and a steroid portion in which typically the 3-position carbon atom of the A-ring of the steroid system carries an O-linked sugar group.

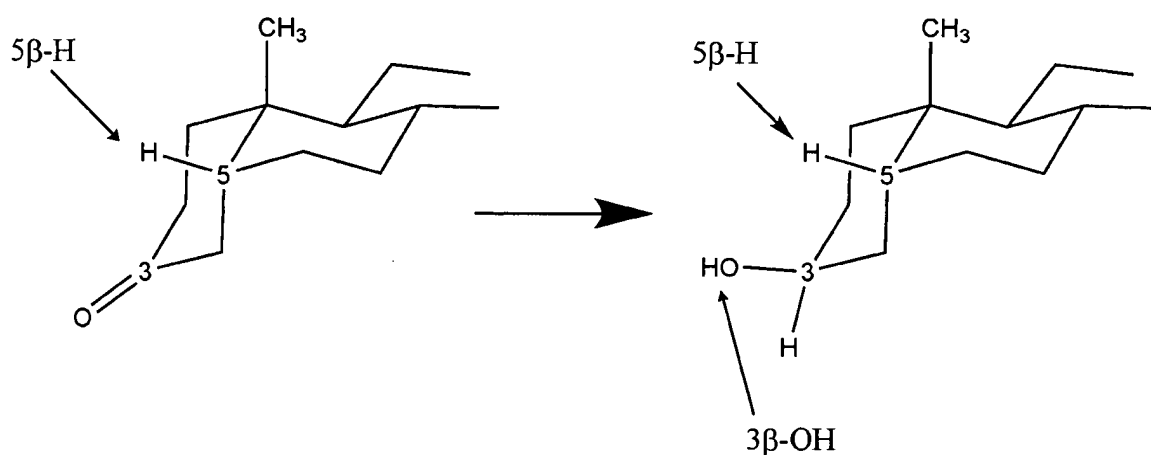
Steroidal sapogenins are thus clearly distinct from sex hormones and other steroids of animal/human origin, such as the androstanes, pregnanes, cholestanes, estrones, etc. This distinction was well understood by the skilled reader.

Since none of the cited prior art documents discloses reduction of a 3-keto steroidal sapogenin, the claims are novel for this reason alone.

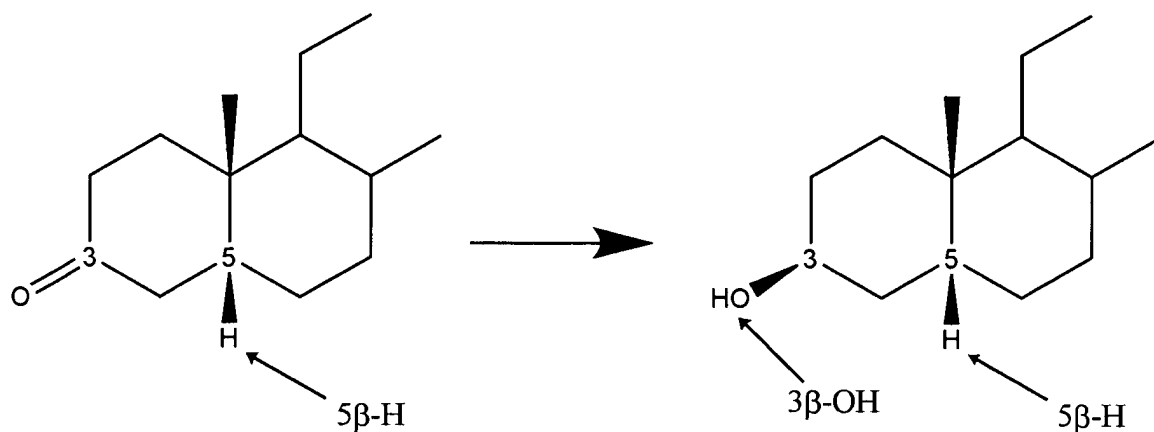
In addition, the claims are novel from the novel reaction features, as will now be discussed.

It is useful at this point to demonstrate diagrammatically the stereochemical change that occurs in the method of claim 1 of the present application.

In the claimed method, a 3-keto group in the 5β -H steroidal sapogenin is converted stereospecifically to a 3β -hydroxy group. This may be shown as follows from a side projection (only A and B rings shown in full for clarity):



Alternatively, from a flattened projection, this reaction can be shown as (again, only A and B rings shown in full for clarity):

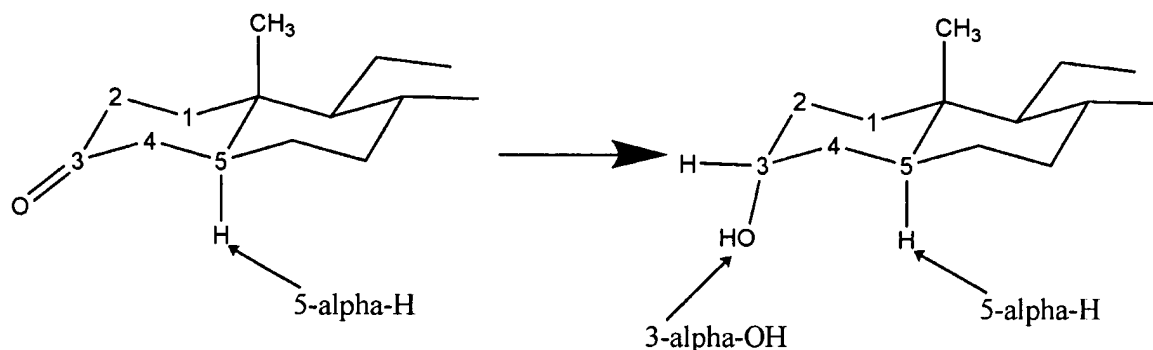


Claims 1- 3 and 6-9 have been rejected as anticipated by the article by Wiebe et al.

Wiebe et al. differs from the claimed method in a number of respects.

This document discloses the reduction of pregnane compound 9 (5 α -pregnane-3,20-dione 9) to compound 10 (3 α -hydroxy-5 α -pregnane-20-one 10).

As mentioned above, the pregnane compounds 9 and 10 are not steroidal sapogenins. Additionally, they are not 5 β -H compounds, as required by the claimed method: the 5-H is in the α position (i.e. downwardly projecting if drawn in the flattened projection above). Furthermore, the claimed reaction requires the conversion of a 3-keto compound stereoselectively to a 3 β -hydroxy compound. In the reaction in Wiebe et al. the 3-keto 5 α -H compound is converted to a 3 α -hydroxy 5 α -H compound. The reaction in Wiebe et al. is shown below (again, showing only the A and B rings in full for clarity):



The differences in configuration and stereochemical outcome between the claimed method and the method of Wiebe et al. should be clear when comparing the diagram immediately above with the diagram shown for the claimed method. Accordingly, the method recited in claims 1-3 and 6-9 of the present application is novel over Wiebe et al.

Claims 1-3 and 6-9 have been rejected as being anticipated by the article by Tal et al.

Tal et al. discloses the reduction of 3,7-diketo cholestane steroids using K-selectride. As mentioned above, the cholestanes are not steroidal sapogenins.

Accordingly, the method recited in claims 1-3 and 6-9 of the present application is novel over Tal et al.

Claims 1-4 and 6-9 have been rejected as anticipated by the article by Gondos et al.

This document relates to the stereoselective and regioselective reduction of androstane, pregnane and estrone steroid ketones by potassium tri-(R, S-s-

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butylborohydride. As mentioned above, the anrostane, pregnane and estrone compounds are not steroidal sapogenins.

Accordingly, the method claimed in claims 1-4 and 6-9 of the present application is novel over Gondos et al.

Claims 1, 5, 8-9 and 15-17 have been rejected as anticipated by the article by Tochtrop et al.

This document discloses a reduction of a cholic acid precursor (compound 20a or 20b) to another (compound 21a or 21b, respectively) using lithium tri-*tert*-butoxaluminumhydride. The cholic acid precursors are not steroidal sapogenins. Although they are steroidal, they are clearly of animal origin.

Furthermore, the reducing agent is an aluminum species, not an organoborane species required by the present invention, and the hydroxy group in each of compounds 21a and 21b is in the α -configuration.

Accordingly, the method recited in claims 1, 5, 8-9 and 15-17 of the present application is novel over Tochtrop et al.

The Examiner has also rejected claims 10-12 as unpatentable over the combination of the article to Wiebe et al. in view of the article by March.

None of the prior art documents and in particular the combination of Wiebe et al. and March suggests that 3β -hydroxy- 5β -H steroidal sapogenins could be prepared by reducing a 3-keto- 5β -H steroidal sapogenin using a hindered organoborane.

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Furthermore, since claims 10-12 depend indirectly upon Claim 1, Claim 1 being patentable as being set forth above, Applicant believes that claims 10-12 are also patentable.

Claims 4 and 12 have been rejected as unpatentable over Gondos et al. In view of the above comments concerning the Gondos et al. reference, Applicant believes that claims 4 and 12 would be patentable as well, being directed to steroidal sapogenins and not the compounds disclosed by Gondos et al.

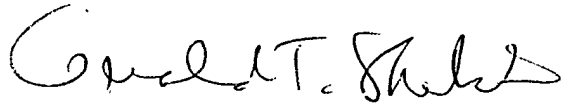
Applicant emphasizes that all of the cited and applied prior art relates to steroids of animal origin, which would not have served as an obvious starting point for any research into steroids of plant origin, let alone the specific class of steroidal sapogenins or the subclass of the 5 β -H steroidal sapogenins. For the above reasons Applicant believes the claims as amended are patentable.

Applicant hereby requests reconsideration and reexamination thereof.

With the above amendments and remarks, this application is considered ready for allowance and applicant earnestly solicits an early notice of same. Should the Examiner be of the opinion that a telephone conference would expedite prosecution of the subject application, he is respectfully requested to call the undersigned at the below listed number,

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Respectfully submitted,

A handwritten signature in black ink, appearing to read "Gerald T. Shekleton". The signature is fluid and cursive, with the first name "Gerald" being more prominent and the last name "Shekleton" following in a similar style.

Dated: April 30, 2008

Gerald T Shekleton

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